

K062066 (pg 1 of 2)

AUG 15 2006

**Summary of Safety and Effectiveness  
Omega™ 3 System**

Proprietary Name:	Omega™ 3 System
Common Name:	Compression Screw System
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT
For Information Contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	July 19, 2006

**Description:**

The Omega™ 3 System is a compression screw system designed to treat various types of fractures of the proximal and distal femur.

**Intended Use:**

The modifications do not alter the intended use of the predicate system as cleared in the referenced premarket notifications. The subject and predicate devices are available sterile and non-sterile intended for use in the temporary stabilization of fractures of the proximal and distal femur. The indications for use for the Omega™ 3 System are provided below.

**Indications for Use:**

The Omega™ Plus, Omega™ 2, and Omega™ 3 Systems are intended for use in the temporary stabilization of types of fractures of the proximal and distal femur. The subject devices are indicated for fixation of proximal and distal femoral fractures including but not limited to:

- Intracapsular and basal neck fractures including transcervical and subcapital fractures

- Intertrochanteric fractures
- Subtrochanteric fractures
- Supracondylar fractures
- Intracondylar fractures
- Osteotomies for patients with diseases or deformities of the hip
- Hip arthrodesis

**Substantial Equivalence:**

The subject Omega™ 3 System shares the same intended use, and basic design concepts as that of the currently available Omega™ Plus System and Omega™ 2 System.

Mechanical testing demonstrated comparable mechanical properties to the predicate components and is substantially equivalent to these devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 15 2006

Howmedica Osteonics Corporation  
% Mr. Francisco Haro  
Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K062066

Trade/Device Name: Omega<sup>TM</sup> 3 System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: KTT

Dated: July 19, 2006

Received: July 21, 2006

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

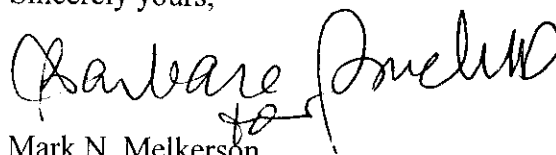
Page 2 – Mr. Francisco Haro

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K062066

510(k) Number (if known):

Device Name: Omega™ 3 System

Indications for Use:

The Omega™ Plus, Omega™ 2, and Omega™ 3 Systems are intended for use in the temporary stabilization of types of fractures of the proximal and distal femur. The subject devices are indicated for fixation of proximal and distal femoral fractures including but not limited to:

- Intracapsular and basal neck fractures including transcervical and subcapital fractures
- Intertrochanteric fractures
- Subtrochanteric fractures
- Supracondylar fractures
- Intracondylar fractures
- Osteotomies for patients with diseases or deformities of the hip
- Hip arthrodesis

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRIH Office of Device Evaluation (ODE)

Barbara P. [Signature]  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

49

510(k) Number K062066